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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,530

04/02/2004

Werner Braun

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/817,530

Applicant(s)

BRAUN ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/11/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Species of claims 8 and 19 in the reply filed on 13 November 2006 is acknowledged. The traversal is on the ground(s) that the generic claim includes sufficiently few species that a search burden and examination of all of the species at one time would not impose a serious burden on the Examiner. This is found persuasive and all claims, 1-22, will be examined herein.

Priority

Priority to US Provisional Application 60/460,769, filed 4 April 2003, is acknowledged.

Information Disclosure Statement

The Information Disclosure Statement filed 20 April 2005 has been partially considered. References 5 (BLAST), 10 (ClustalW), 13 (Emotif Maker), and 43 (Prosite Database) have not been considered, as they lack a publication date. The only date listed is the retrieval from the Internet date, which does not constitute a publication date.

Drawings

The Drawings filed 29 September 2004 are accepted.

Sequence Compliance

This application contains sequences in Figure 9A with no associated SEQ ID NOs. Therefore this application contains sequence disclosures that are encompassed by the definitions

Art Unit: 1631

for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).

Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example page 18. Applicant is responsible for correcting all instances of embedded hyperlinks in the specification. See MPEP § 608.01.

The use of the trademark BLAST, for example, at page 18 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Applicant should be aware of all instances of trademarks in the specification.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-22 are directed to a method and computer program for use in sequence data analysis comprising various method steps, such as, providing physical-chemical property (PCP) descriptors, describing sequence alignments in terms of eigenvector, analyzing PCP alignments, and defining PCP motifs. The method steps in the instant claims fall into a category of judicial exception, as they merely recite manipulations of data (abstract ideas/algorithms) and do not recite either a physical transformation of matter nor a practical application [i.e. concrete, tangible, and useful result], as required under 35 USC 101 for a judicial exception to become statutory. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a concrete, tangible, and useful result (i.e. a practical application). The steps of providing physical-chemical property (PCP) descriptors, describing sequence alignments in terms of eigenvectors, analyzing PCP alignments, and defining PCP motifs are not deemed a “useful, concrete, and tangible result.” Therefore, no actual, concrete result is recited in the claims, nor is any useful result “produced” in a tangible form useful to one skilled in the art. For these reasons, the claims are not statutory.

This rejection could be overcome by amending the claims to recite that a result of the method is “displayed” or “outputted” (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of

Art Unit: 1631

matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite, "analyzing the conservation property data for each of the PCP described sequences...where the physical-chemical properties are conserved based on at least the relative entropy determined for each column; and defining one or more PCP motifs in the multiple sequence alignment...where the physical-chemical properties are conserved according to at least one eigenvector". It is unclear what the analyzing of the conservation property where the PCPs are conserved based on entropy and the final step of the PCPs based on eigenvectors have to do with one another and what the final step has to do with analysis of sequence data. The outcome of the method is unclear. Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1631

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatarajan et al. (J. Mol. Model (2001) Vol. 7, pages 445-453; PTO Form 1449 reference) in further in view of Zhu et al. (Bioinformatics (2000) Vol. 16, pages 950-951; PTO Form 1449 reference), as evidenced by Mathura et al. (Structural Biology Symposium, May 2002, Poster Abstract; PTO Form 1449 reference).

The instant claims are drawn to a method and computer program for sequence data analysis comprising providing a multiple sequence alignment comprising a column, providing

Art Unit: 1631

PCP (physical-chemical property) descriptors corresponding to eigenvectors, describing each amino acid in terms of the PCPs, analyzing the PCP alignments to yield conservation property data, and analyzing the conservation property. The claims are further drawn to entropy values with predetermined limit, using PCP motifs to search a database for related sequence segments, using positional scoring to generate matrices, and ranking proteins.

Venkatarajan et al. teach a method for deriving new quantitative descriptors for the 20 naturally occurring amino acids based upon multi-dimensional scaling of 237 physical-chemical properties (page 445, abstract). Venkatarajan further teaches that the descriptors provide a quantitative means to identify property motifs in sequences of protein families. A property of an amino acid is normalized such that the standard deviation is 0 (page 446, column 1). Each amino acid is represented by an eigenvector which has an associated eigenvalue (page 446, column 1). Once the vectors are calculated, a property distance matrix is established (page 446, column 2). Similarity matrices are developed based upon structural similarity (page 450, column 2).

Venkatarajan does not teach the multiple sequence alignment whereby a column of aligned amino acids and/or gaps is represented or using a sequence motif to search a database, or defining a PCP motif as a series of matrices. However, Zhu et al. teach a software tool for pattern recognition in multiple aligned protein sequences called MASIA (page 950, abstract). MASIA converts a sequence to a properties matrix that can be scanned in both the vertical and horizontal steps. Patterns are recognized based upon statistical significance of their occurrence (abstract). Further specifics include the conversion of sequence alignment matrix to a property matrix, in which motifs are identified. The matrix of properties is scanned in vertical and horizontal steps to search for combinations of conserved properties (page 950, column 2). The

Art Unit: 1631

three major components of the program are the property library, statistical evaluation for determining property conservation and the command-line macro (page 950, column 2). The methods are based upon probability entropy to show significant conservation in a column (page 950, column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the PCP descriptors of Venkatarajan with the alignment methods of Zhu in sequence data analysis. One would have been motivated to do so, as evidenced by Mathura et al., who use MASIA with PCPs for functional annotation of genomic sequences based upon discreet motifs (abstract).

Venkatarajan and Zhu do not specifically teach Bayesian ranking, as in claim 8 and 19. However, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have employed Bayesian scoring, as an alternative to similarity scoring, as it is well-known in the art the Bayesian analysis is used to evaluate distributions in scores.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Art Unit: 1631

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

February 4, 2007

Lori A. Clow, Ph.D.

Art Unit 1631

Lori A. Clow
Patent Examiner
2/4/07